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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,520	12/14/2001	Gene Parunak	10255-018-999	3929

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EXAMINER	
SINES, BRIAN J	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,520	PARUNAK ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-9,11,12,14-16,18-21,23-26,30-33 and 38-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-9,11,12,14-16,18-21,23-26,30-33 and 38-56* is/are rejected.

7)☒ Claim(s) *14 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 14 and 16 are objected to because of the following informalities: Claims 14 and 16 are each dependent on canceled claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6 - 9, 11, 12, 14 - 16, 18 - 21, 23 - 26, 30 - 33 and 38-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al. (U.S. Pat. Pub. No. US 2002/0055167 A1) (hereinafter "Pourahmadi") in view of Handique et al. (U.S. Pat. No. 6,130,098 A) (hereinafter "Handique").

Regarding claims 1, 9, 15, 18 – 20, 26, 30, 40 and 53, Pourahmadi teaches an apparatus (cartridge 101) comprising: a sample port (103); a first channel (105); a lysing zone (lysing chamber 119); and second channel (121) leading downstream from the enrichment zone (see

paragraphs 0044 & 0048; figure 2). Pourahmadi teaches the incorporation of an input means for facilitating the introduction of reagents and test samples into the device (see col. 11, lines 1 – 53). Pourahmadi further teaches that the apparatus can also incorporate one or more filters (e.g., a partitioning structure) for capturing sample components, e.g., cells, spores or microorganisms to be lysed. The filters may also be used for removing particulates, cell debris and protein solids from the sample. The filters may be within any region, e.g., within the fluid passages or channels leading between regions or within a particular interactive region (see paragraph 0099). Thus, it would have been obvious to a person of ordinary skill in the art to incorporate an enrichment zone or chamber, which comprises a flow-through filter member, positioned upstream of the lysing chamber of the apparatus. In addition, Pourahmadi teach the incorporation of specific electrode configurations comprising a detection zone to allow for the electrochemical detection of chemical constituents in a processed sample (see paragraph 0135). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a detection zone disposed downstream of the enrichment zone to monitor the chemical composition of processed samples.

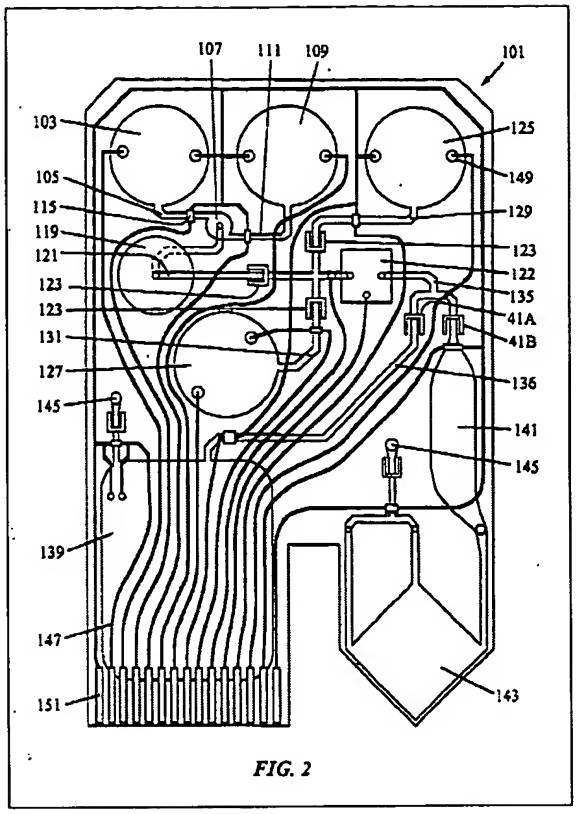

FIG. 2

Pourahmadi does not specifically teach the further incorporation of a gas actuator to facilitate sample fluid flow within the disclosed apparatus. Pourahmadi does teach that a fluid sample may be introduced into the cartridge by a variety of means, manual or automated (see paragraph 0078). Pourahmadi teaches that for automated sample introduction, additional cartridge design features are employed and, in many cases, impart specimen accession functionality directly into the cartridge (see paragraph 0080). Pourahmadi does further teach that a fluid motive source comprising a pneumatic pressure source can be internally incorporated within the cartridge apparatus for facilitating sample fluid transport (see paragraph 0067).

Handique teaches a thermopneumatic apparatus comprising a gas actuator for facilitating fluid transport in microfluidic devices (see col. 13, line 60 – col. 15, line 40; figures 3A, 3B, 4A & 4B). As shown in figure 4B, the system taught by Handique comprises a thermopneumatic

actuating system denoted by 180, a hydrophobic gas vent (170), a positioning element (hydrophobic region 140), and an outlet, which is located to the right of the sample (160) and at the end of the channel containing the sample, from which the sample is transferred for further processing, such as to a lysing chamber for cell lysing, when integrated within an analytical microfluidic system.

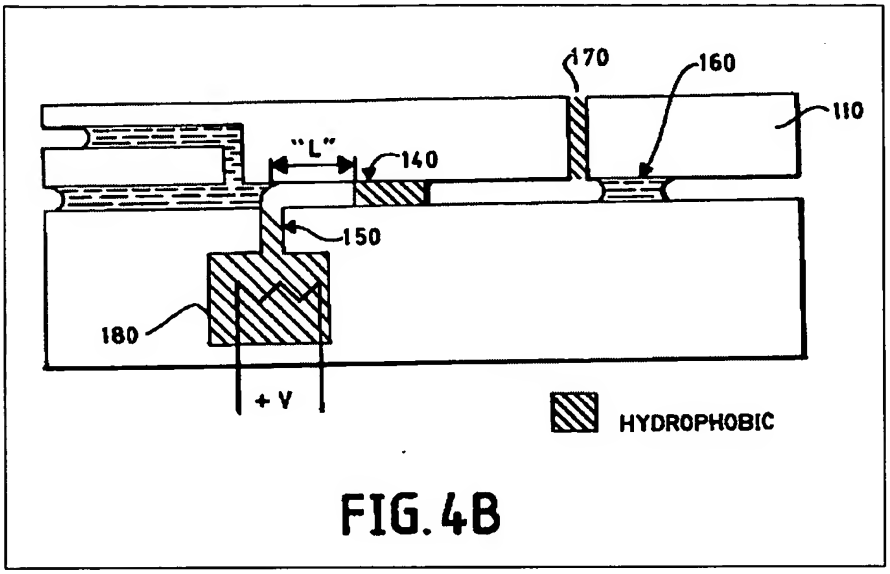

FIG. 4B

Hence, as evidenced by Handique, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating such a thermopneumatic fluid transport system with a microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a thermopneumatic fluid transport system with a microfluidic apparatus for facilitating effective sample fluid transport.

Regarding claims 11 and 12, Pourahmadi teaches the incorporation of a mixing module 107 (see figure 2).

Regarding claims 3 & 21, Pourahmadi teaches that the flow-through or partitioning member comprises a filter, which is inherently anticipated to sieve particles from the sample (see paragraph 0099).

Regarding claims 6, 7, 23, 24, 44 – 46 and 54 – 56, Handique suggests the incorporation of valves, which are well known in the art, with the hydrophobic vents (70 & 170) for opening and closing the vents for facilitating sample fluid transport. Handique also teaches the use of thermally-actuated valves (see col. 14, lines 51 – 57; col. 16, lines 40 – 61; figures 3A, 3B, 4A & 4B) (see MPEP 2144.03). In addition, Pourahmadi also teaches the incorporation of various valves within the disclosed microfluidic apparatus to provide means for controlling fluid transport within the disclosed apparatus (see, e.g., paragraph 0052). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a plurality of valves within the apparatus as claimed in order to facilitate effective sample fluid flow within apparatus.

Regarding claims 8, 25, 33, 39 and 41 – 43, Pourahmadi does not specifically teach the complete device structural configuration as claimed. However, Handique teaches that the various features of the microfluidic apparatus are microfabricated and integrated within silicon and glass substrates (see col. 3, line 46 – col. 4, line 10). Pourahmadi also teaches that the disclosed apparatus is microfabricated utilizing glass or silicon structural members as well (see paragraphs 0097 & 0098). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in microfabricating an integrated microfluidic apparatus as claimed (see MPEP § 2143.02). Therefore, it would a have been obvious to a person of ordinary skill in the art to microfabricate an integrated microfluidic apparatus as claimed.

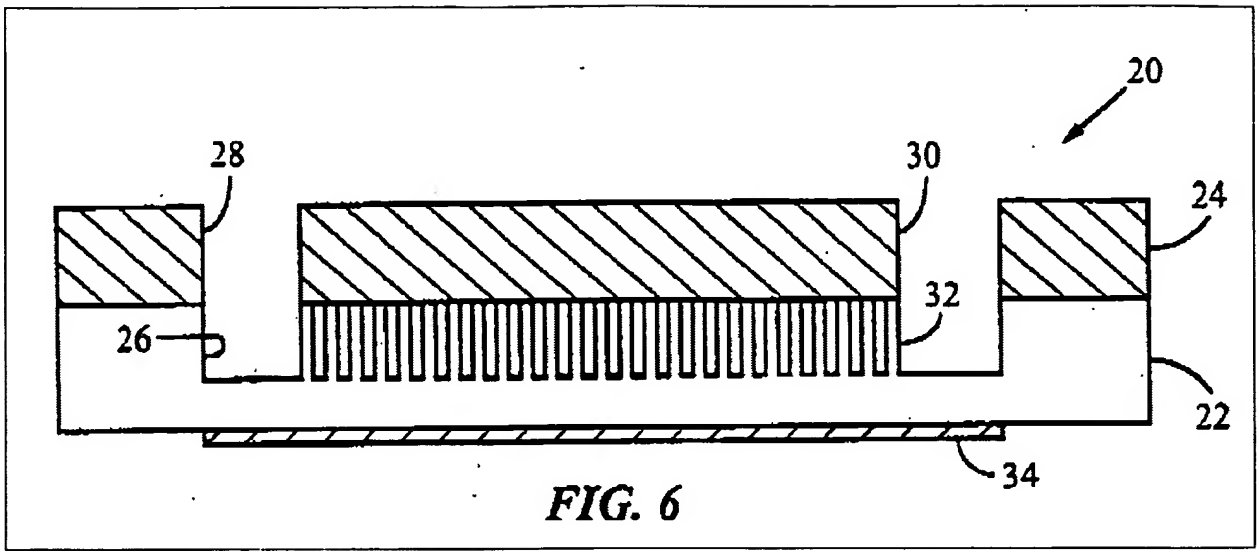

FIG. 6

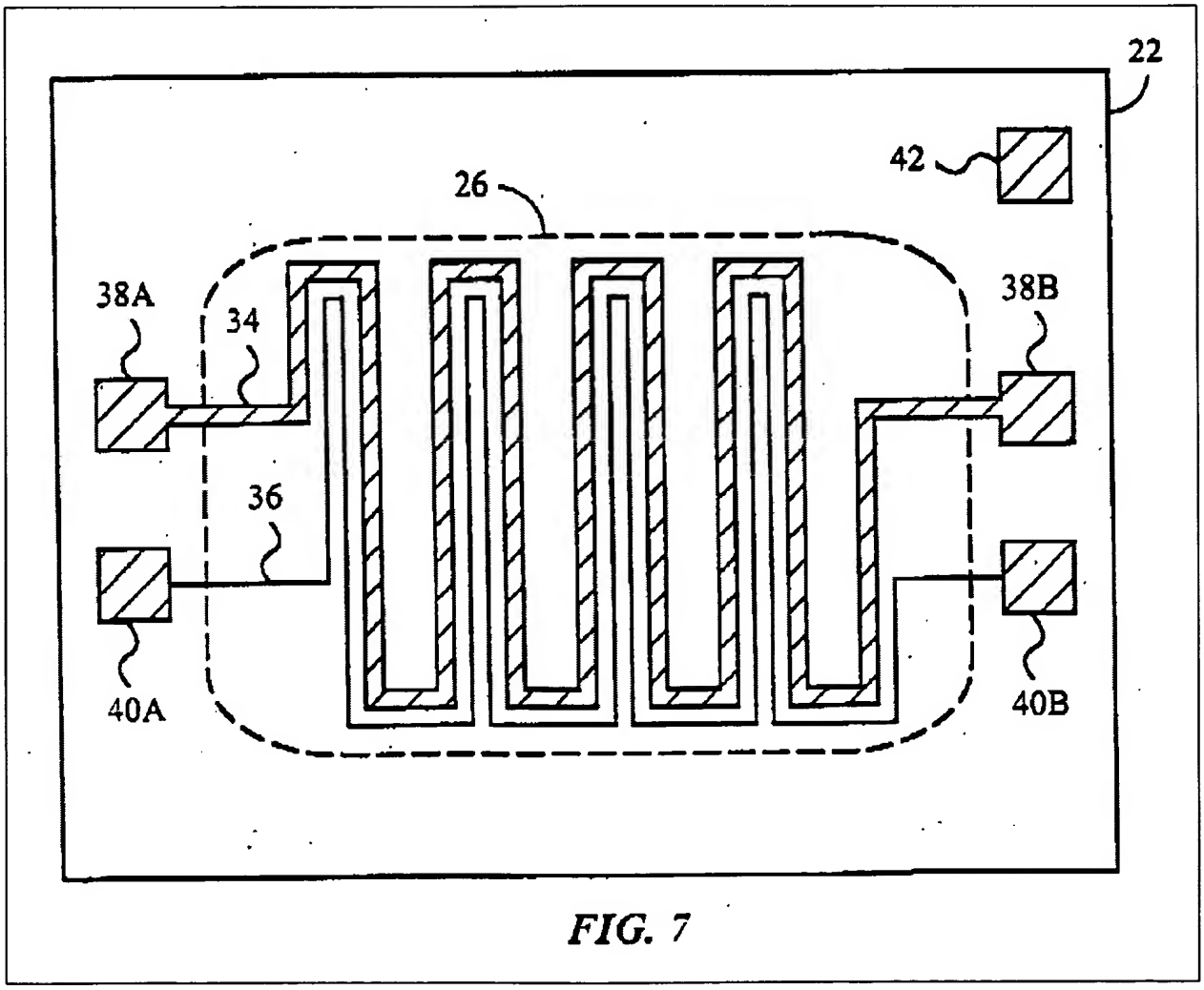

FIG. 7

Handique teaches a microfluidic device configuration comprising a lower silicon dioxide substrate 810B and an upper glass substrate 810A. The bottom surface of the upper glass substrate 810A has channels and chambers etch into it. The lower silicon substrate comprises a heating element 891 (see col. 20, lines 5 – 13; col. 26, lines 1 – 29; figure 8A). The resistive heating elements comprise a metallic aluminum film (see col. 20, lines 13 – 22). The substrate layers are bonded together (see, e.g., col. 21, lines 29 – 33).

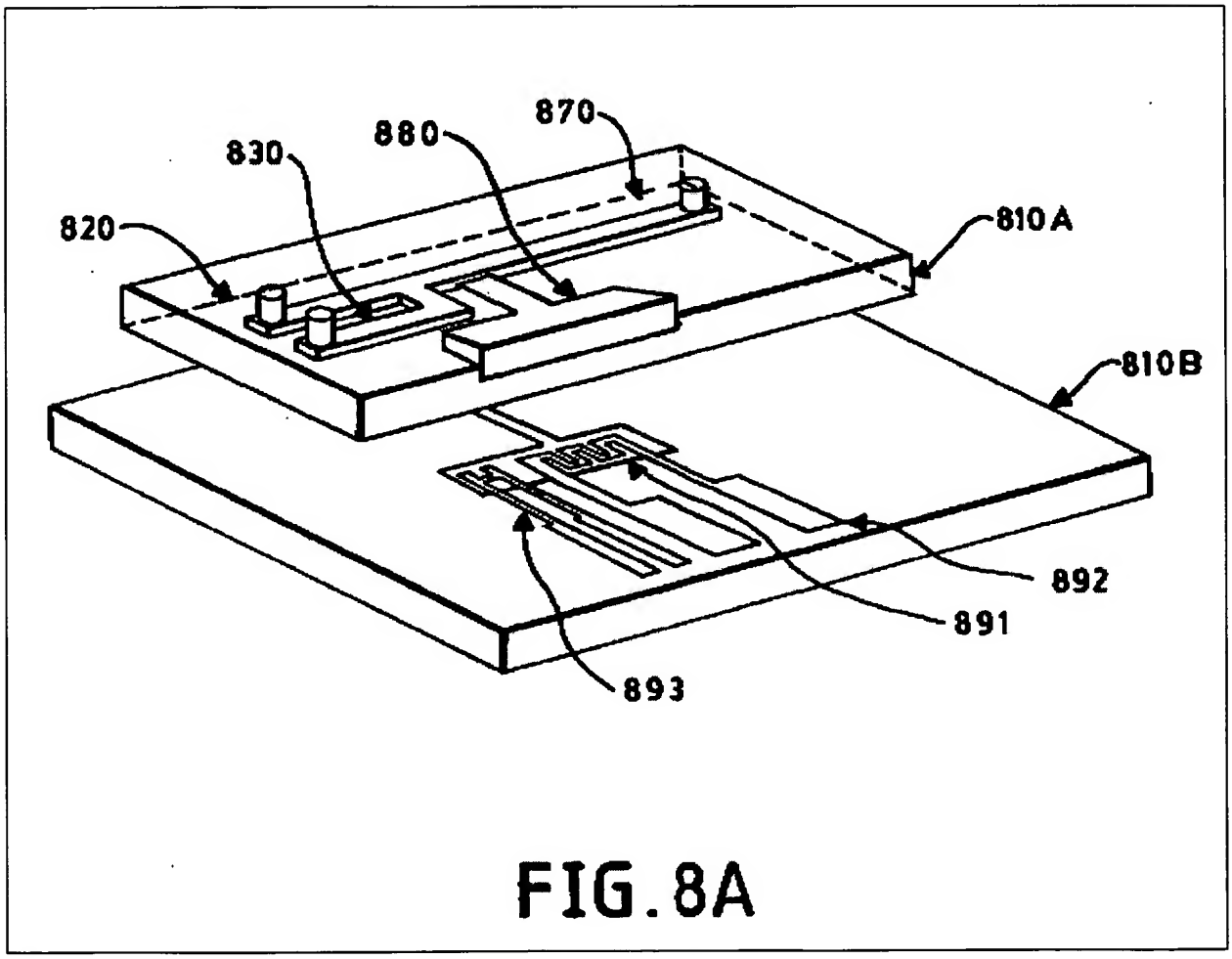

FIG. 8A

Handique further teaches a device configuration comprising a lower substrate 300 having a base comprising glass and an upper substrate 200 comprising silicon. The top substrate 200 has microchannels 100 (see col. 13, lines 48 – 59).

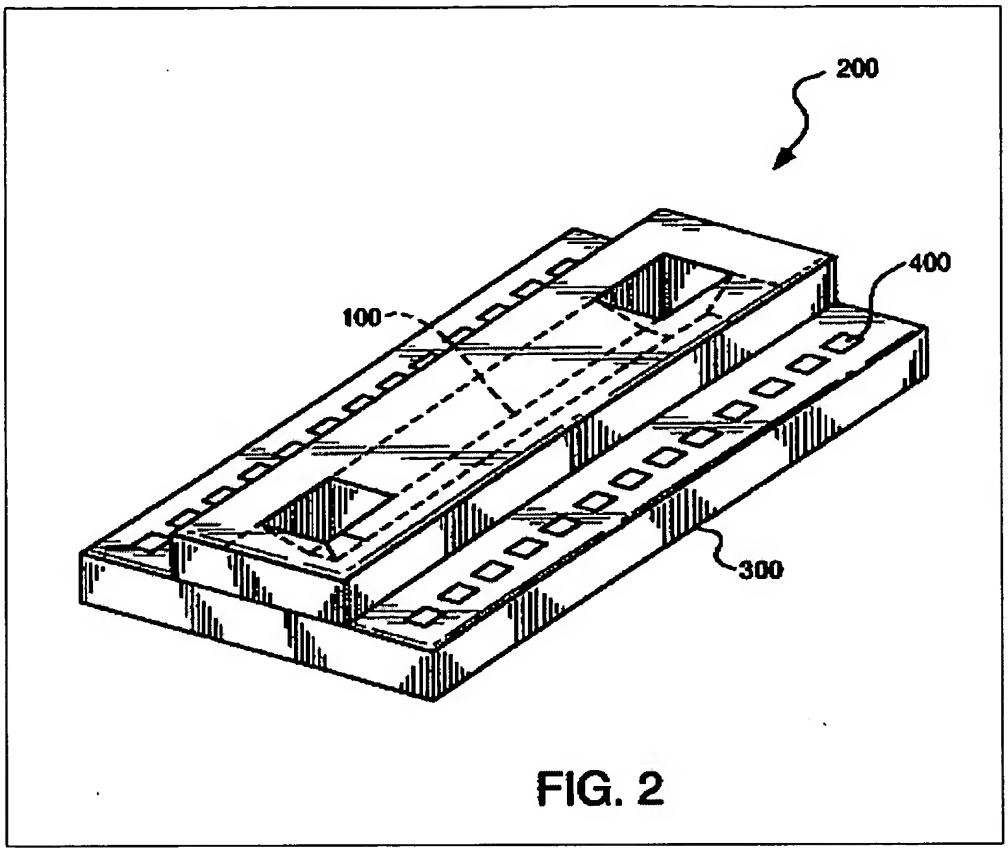

FIG. 2

As indicated in figure 5, a plurality of successive heaters can be arranged in a substrate and along the length of a channel for facilitating fluid transport through the channel (see col. 15, line 41 – col. 16, line 23).

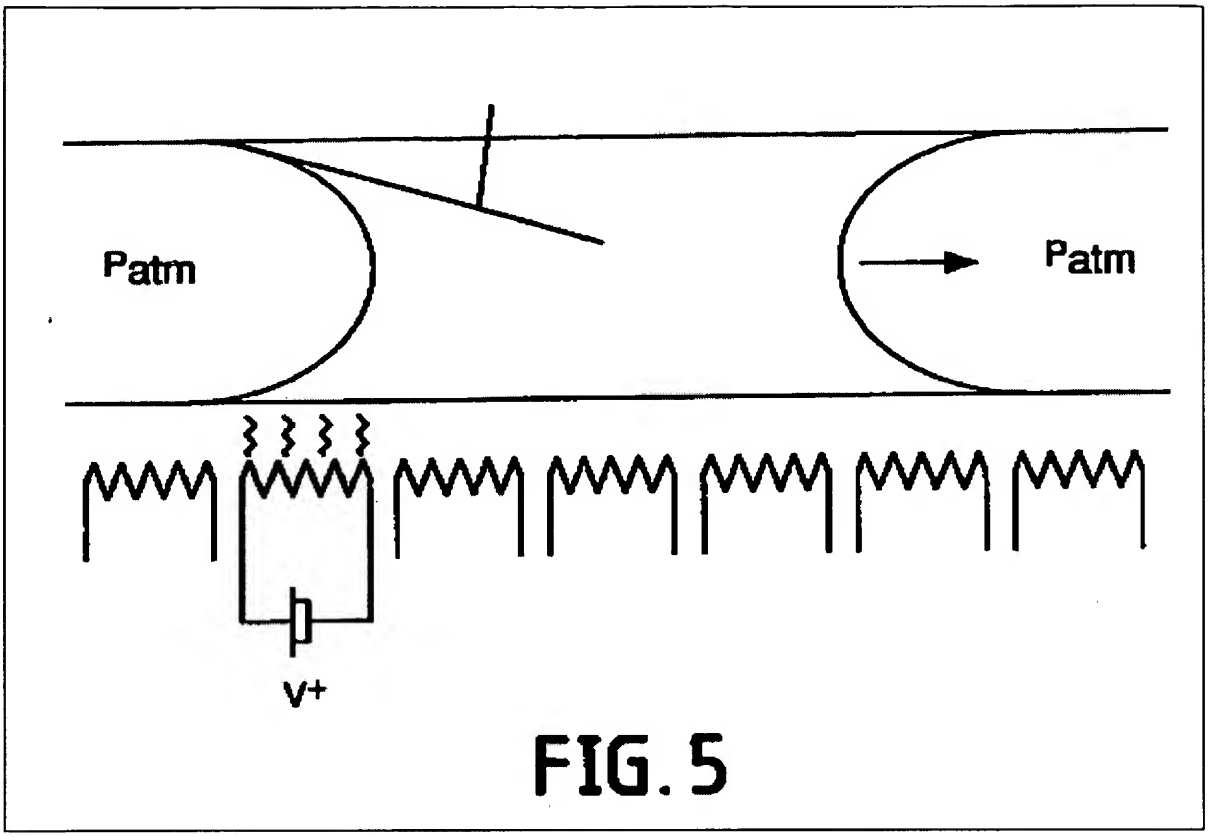

FIG. 5

Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the device configuration within the disclosed microfluidic device as claimed to facilitate effective fluid sample transport.

Regarding claims 14 & 31, Pourahmadi teaches the incorporation of a cell lysis mechanism utilizing an electrical field to facilitate cell lysis and extraction (see paragraph 0112).

Regarding claims 16 & 32, Pourahmadi teaches the incorporation of a DNA manipulation or polymerase chain reaction zone (reaction chamber 143) for PCR amplification (see paragraph 0054).

Regarding claims 38, 47 – 49 and 52, Pourahmadi teaches that the flow-through component 122 can comprise a chamber comprising an absorbent material, such as filters, beads, fibers, membranes, polymers and gels (see paragraph 0113; figure 2). With respect to

claims 47 and 48, it would have been obvious to a person of ordinary skill in the art to incorporate the dimensions claimed since these dimensional characteristics of filter materials are well known in the art.

Regarding claims 12, 50 and 51, these claims are considered statements of intended use or process limitations. These claims do not positively recite any further structural limitations for the claimed device.

Response to Arguments

Regarding the rejection of the present claims under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi in view of Handique, applicant's arguments filed 6/26/2006 have been fully considered but they are not persuasive. The applicant alleges that the combined references do not teach each and every limitation of the claimed invention. The applicant alleges that the two devices taught by the prior art operate using different fluid transport mechanisms. In response to applicant's argument that the disclosed teachings of each of the references are essentially incompatible since Pourahmadi teaches a continuous flow-type device and Handique teaches a device that operates by manipulating microdroplets, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In*

re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both references pertain to microfluidic device that process similar samples for analysis. The prior art devices differ essentially in the fluid transport mechanisms used within each device. Pourahmadi does teach that the disclosed apparatus is capable of processing sample volumes of 10 μL or less (see paragraphs 0077 and 0163). Pourahmadi does teach that current microfluidic devices are capable of processing large, i.e., microliter, and small sample volumes, i.e., picoliter and nanoliter fluid volumes (see paragraphs 0007 – 0010; figure 1). Pourahmadi does indicate that the disclosed device is capable of performing immunoassays that, as shown in figure 1, use approximately nanoliter sample volumes and less (see paragraph 0087). Handique also teaches the use of sample volumes of between approximately 0.01 and 100 nanoliters (see col. 7, lines 53 – 63). Thus, both microfluidic devices can process similar sample volumes. Furthermore, both disclosed microfluidic devices can be made using the same fabrication techniques, e.g., photolithography (see Handique, col. 4, lines 7 – 10; Pourahmadi, paragraph 0098). Pourahmadi does teach the use of fluid flow mechanisms, such a pump, integrated within the device itself (see paragraphs 0020 and 0139). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating such a thermopneumatic fluid

transport system, as taught by Handique, with the microfluidic apparatus of Pourahmadi. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage, or expected beneficial result would have been produced by their combination. See *In re Sernaker*, 702 F.2d 989, 994 – 995, 217 USPQ 1, 5, 6 (Fed. Cir. 1983) (see MPEP § 2144). The Court has recognized that an artisan is presumed to have skill, rather than lack of skill. See *In re Sovish*, 226 USPQ 771 (Fed. Cir. 1985). In addition, the rationale to support an obviousness rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle (see MPEP § 2144.02). Handique does teach that the disclosed fluid transport mechanism significantly improves fluid sample processing overcoming liquid handling inefficiencies within conventional analytical microfluidic devices (see col. 3, lines 33 – 64). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a thermopneumatic fluid transport system with the disclosed microfluidic apparatus as claimed for facilitating effective sample fluid transport and processing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).